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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ASTRAZENECA AB; AKTIEBOLAGET HÄSSLE; ASTRAZENECA LP; KBI INC.; and KBI-E INC.,	Honorable Joel A. Pisano, U.S.D.J.
	Civil Action No. 10 CV 1017 (JAP) (LHG)
Plaintiffs,	
v.	**DEFENDANTS SUN PHARMA GLOBAL FZE'S, SUN PHARMACEUTICAL INDUSTRIES, INC.'S and SUN PHARMACEUTICAL INDUSTRIES, LTD.'S ANSWER, AFFIRMATIVE DEFENSES, COUNTERCLAIM AND JURY DEMAND**
SUN PHARMA GLOBAL FZE, SUN PHARMACEUTICAL INDUSTRIES, INC., SUN PHARMA GLOBAL INC., SUN PHARMACEUTICAL INDUSTRIES, LTD., and CARACO PHARMACEUTICAL LABORATORIES, LTD.,	
Defendants.	

Defendants Sun Pharma Global FZE ("Sun FZE"), Sun Pharmaceutical Industries, Ltd., and Sun Pharmaceutical Industries, Inc. (collectively, "Sun") answer the Complaint for Patent Infringement of Plaintiffs AstraZeneca AB, Aktiebolaget Hässle, AstraZeneca LP, KBI Inc., and KBI-E Inc. (together, "Plaintiffs") as follows:

AS TO JURISDICTION AND VENUE

1. This is an action for patent infringement arising under the Patent and Food and Drug laws of the United States, Titles 35 and 21, United States Code. Jurisdiction and venue are based on 28 U.S.C. §§ 1331, 1338(a), 1391(b), 1391(c), 1400(b), 2201, 2202 and 35 U.S.C. § 271.

ANSWER: Paragraph 1 states legal conclusions to which no response is required. To the extent a response is required, Sun admits that Plaintiffs' Complaint purports to be an action for patent infringement but denies that Plaintiffs are entitled to any relief. Further, Sun will not contest personal jurisdiction or venue in this District for purposes of this case only.

2. On information and belief, Sun Pharma Global FZE, Sun Pharmaceutical Industries, Inc., Sun Pharma Global Inc., Sun Pharmaceutical Industries, Ltd., and Caraco Pharmaceutical Laboratories, Ltd. (collectively "Sun") have been and are engaging in activities directed toward infringement of United States Patent Nos. 5,877,192 (the "'192 patent") and 6,143,771 (the "'771 patent"), by, *inter alia*, submitting an abbreviated new drug application designated ANDA No. 20-882 and by submitting a Drug Master File ("DMF") seeking FDA's approval to manufacture commercially its proposed product called "Esomeprazole Sodium for Injection, 20 mg/vial and 40 mg/vial" (hereinafter referred to as "Esomeprazole Sodium I.V. Product") containing the active ingredient esomeprazole sodium.

ANSWER: Sun admits that Sun FZE submitted Abbreviated New Drug Application No. 200-882 seeking FDA approval to engage in the commercial manufacture, use or sale of Esomeprazole Sodium for Injection, 20 mg/vial and 40 mg/vial. Sun further admits that Sun Pharmaceutical Industries, Ltd. holds a Drug Master File for Esomeprazole Sodium. Sun denies the remaining allegations of this Paragraph.

3. In Sun's notice letter entitled "Notification Pursuant to § 505(j)(2)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.S. 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95" (hereinafter referred to as the "January 15, 2010 Letter"), Sun has indicated that it intends to market its Esomeprazole Sodium I.V. Product before the expiration of the '192 and '771 patents.

ANSWER: Sun admits that Sun FZE sent a letter entitled "Notification Pursuant to § 505(j)(2)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95," on January 15, 2010. Sun denies the remaining allegations of this Paragraph.

4. Sun's submission of ANDA No. 20-882 and the DMF, in addition to service of its January 15, 2010 Letter, indicates a refusal to change its current course of action.

ANSWER: Sun is without knowledge or information sufficient to form a belief as to the truth of the allegation concerning any Defendant's "current course of action" because that phrase is vague and undefined in context. Sun therefore denies the allegations of this Paragraph.

5. There has been and is now an actual controversy between Sun and Plaintiffs as to whether Sun infringes the '192 and '771 patents.

ANSWER: Sun admits that there is an actual controversy between Sun and Plaintiffs with respect to whether Sun infringes the '192 and '771 patents. Sun is without knowledge or information sufficient to form a belief as to the truth of the allegation that there "has been" such an actual controversy, because that phase is vague and undefined in context. Sun therefore denies the same.

AS TO THE PARTIES

6. Plaintiff AstraZeneca AB is a company organized and existing under the laws of Sweden, having its principal place of business at Södertälje, Sweden. AstraZeneca AB was a corporate name change from Astra Aktiebolaget.

ANSWER: Admitted, on information and belief, that AstraZeneca AB is a company organized and existing under the laws of Sweden, having a place of business at Södertälje, Sweden. Sun is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this Paragraph and therefore denies the same.

7. Plaintiff Aktiebolaget Hässle ("Hässle") is a company organized and existing under the laws of Sweden, having its principal place of business at Mölndal, Sweden.

ANSWER: Admitted, on information and belief.

8. Plaintiff AstraZeneca LP is a limited partnership organized under the laws of Delaware having its principal place of business at Wilmington, Delaware. AstraZeneca LP holds an approved New Drug Application from the United States Food and Drug Administration ("FDA") for an esomeprazole magnesium formulation which it sells under the name NEXIUM®.

ANSWER: Sun is without knowledge or information sufficient to form a belief as to the truth of the allegations in this Paragraph and therefore denies the same.

9. Plaintiff KBI Inc. ("KBI") is a Delaware corporation having its principal place of business at Whitehouse Station, New Jersey.

ANSWER: Admitted, on information and belief.

10. Plaintiff KBI-E Inc. ("KBI-E") is a Delaware corporation, having its principal place of business at Wilmington, Delaware. KBI and KBI-E have exclusive rights in the United States to patents-in-suit.

ANSWER: Admitted, on information and belief, that KBI-E Inc. is a Delaware corporation with a place of business at Wilmington, Delaware. Sun is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph and therefore denies the same.

11. On information and belief, defendant Sun Pharma Global FZE is a company organized and existing under the laws of the United Arab Emirates having a principal place of business at Office #43, SAIF Zone, P.O. Box 122304, Shariah, United Arab Emirates. On information and belief, Sun Pharma Global FZE is a wholly-owned subsidiary of Sun Pharma Global Inc. which is in turn a wholly-owned subsidiary of Sun Pharmaceutical Industries, Ltd. On information and belief, Sun Pharma Global FZE manufactures numerous generic drugs for sale and use throughout the United States, including this judicial district. On information and belief, Sun Pharma Global FZE has availed itself of the legal protections of the State of New Jersey, having asserted counterclaims in lawsuits filed in the United States District Court for the District of New Jersey.

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent a response is required, Sun admits that Sun FZE is a company organized and existing under the laws of the United Arab Emirates having a principal place of business at Office #43, SAIF Zone, P.O. Box 122304, Shariah, United Arab Emirates. Sun admits that Sun FZE is a wholly owned subsidiary of Sun Pharma Global Inc. Sun further states that Sun Pharma Global FZE does not contest personal jurisdiction in this District for purposes of this case only. Sun denies the remaining allegations in this Paragraph.

12. On information and belief, defendant Sun Pharmaceutical Industries, Inc. is a company organized and existing under the laws of Michigan having a principal place of business at 279 Prospect Plains Rd., Cranbury, New Jersey 08512. Based on information provided in Sun's January 15, 2010 Letter, Sun Pharmaceutical Industries, Inc. is authorized to accept service of process on behalf of Sun. On information and belief, Sun Pharmaceutical Industries, Inc. is a wholly-owned subsidiary of Sun Pharmaceutical Industries, Ltd. On information and belief, Sun Pharmaceutical Industries, Inc. manufactures numerous generic drugs for sale and use throughout the United States, including this judicial district. On information and belief, Sun Pharmaceutical Industries, Inc. has availed itself of the legal protections of the State of New Jersey, having asserted counterclaims in lawsuits filed in the United States District Court for the District of New Jersey.

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent a response is required, Sun admits that Sun Pharmaceutical Industries, Inc. is a corporation organized and existing under the laws of Michigan having a principal place of business at 279 Prospect Plains Rd., Cranbury, New Jersey 08512. Sun further admits that Sun FZE's January 15, 2010 Notice Letter states, in part, that Sun FZE "certifies pursuant to 21 C.F.R. § 314.95(c)(7) that: John L. Dauer, Jr. Esq., Chief Patent Counsel, Sun Pharmaceutical Industries Inc., 270 Prospect Plains Rd., Cranbury, NJ 08512 is hereby authorized to accept service of process on behalf of [Sun FZE] in connection with its ANDA No. 200882." Sun further admits that Sun Pharmaceutical Industries, Inc. is a wholly-owned subsidiary of Sun Pharmaceutical Industries, Ltd. Sun further states that Sun Pharmaceuticals Industries, Inc. does not contest personal jurisdiction in this District for purposes of this case only. Sun denies the remaining allegations in this Paragraph.

13. On information and belief, defendant Sun Pharma Global Inc. is a company organized and existing under the laws of British Virgin Islands having a place of business at International Trust Building, P.O. Box No. 659, Road Town, Tortola, British Virgin Islands. On information and belief, Sun Pharma Global Inc. is a wholly-owned subsidiary of Sun Pharmaceutical Industries, Ltd. On information and belief, Sun Pharma Global Inc. manufactures numerous generic drugs for sale and use throughout the United States, including this judicial district. On information and belief, Sun Pharma Global Inc. has availed itself of the legal protections of the State of New Jersey, having asserted counterclaims in lawsuits filed in the United States District Court for the District of New Jersey.

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent a response is required, Sun admits that Sun Pharma Global Inc. is a company organized and existing under the laws of British Virgin Islands having a place of business at International Trust Building, P.O. Box No. 659, Road Town, Tortola, British Virgin Islands. Sun further admits that Sun Pharma Global Inc. is a wholly-owned subsidiary of Sun Pharmaceutical Industries, Ltd. Sun otherwise denies the allegations of this Paragraph and denies that Sun Pharma Global Inc. is a proper defendant in this action.

14. On information and belief, defendant Sun Pharmaceutical Industries, Ltd. is a company organized and existing under the laws of India having a principal place of business at Acme Plaza, Andheri -- Kurla Rd., Andheri (E), Mumbai, India 400059. On information and belief, Sun Pharmaceutical Industries, Ltd. manufactures numerous generic drugs for sale and use throughout the United States, including this judicial district. On information and belief, Sun Pharmaceutical Industries, Ltd. has availed itself of the legal protections of the State of New Jersey, having asserted counterclaims in lawsuits filed in the United States District Court for the District of New Jersey.

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent a response is required, Sun admits that Sun Pharmaceutical Industries, Ltd. is a company organized and existing under the laws of India having a principal place of business at Acme Plaza, Andheri -- Kurla Rd., Andheri (E), Mumbai, India 400059. Sun further states that Sun Pharmaceutical Industries, Ltd. does not contest personal jurisdiction in this District for purposes of this case only. Sun denies the remaining allegations in this Paragraph.

15. On information and belief, defendant Caraco Pharmaceutical Laboratories, Ltd. is a company organized and existing under the laws of Michigan having a principal place of business at 1150 Elijah McCoy Drive, Detroit, MI 48202. On information and belief, Caraco Pharmaceutical Laboratories, Ltd. is a subsidiary of Sun Pharmaceutical Industries, Ltd. and a majority of Caraco Pharmaceutical Laboratories, Ltd.'s stock is owned by Sun Pharmaceutical Industries, Ltd. On information and belief, Caraco Pharmaceutical Laboratories, Ltd. manufactures numerous generic drugs for sale and use throughout the United States, including this judicial district. On information and belief, Caraco Pharmaceutical Laboratories, Ltd. has availed itself of the legal protections of the State of New Jersey, having asserted counterclaims in lawsuits filed in the United States District Court for the District of New Jersey.

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent a response is required, Sun admits that Caraco Pharmaceutical Laboratories, Ltd. is a company organized and existing under the laws of Michigan having a principal place of business at 1150 Elijah McCoy Drive, Detroit, MI 48202. Sun further admits that, as of this date, a majority of Caraco Pharmaceutical Laboratories, Ltd.'s stock is owned by Sun Pharmaceutical Industries, Ltd. Sun denies the remaining allegations in this paragraph and denies that Caraco Pharmaceutical Laboratories, Ltd. is a proper defendant in this lawsuit.

16. On information and belief, Sun is doing business in New Jersey, has continuous and systematic contacts with New Jersey, has engaged in activities related to the subject matter of this action and is subject to personal jurisdiction in this judicial district.

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent a response is required, Sun states that Sun Pharma Global FZE, Sun Pharmaceutical Industries, Ltd. and Sun Pharmaceuticals, Inc. do not contest personal jurisdiction in this District for purposes of this case only. Sun denies the remaining allegations of this Paragraph.

AS TO THE FIRST CLAIM FOR RELIEF: '192 PATENT

17. AstraZeneca AB, Hässle, AstraZeneca LP, KBI and KBI-E (collectively, "Plaintiffs") reallege paragraphs 1-16 above as if set forth specifically here.

ANSWER: Sun incorporates and repeats its responses to paragraphs 1-16 above.

18. The '192 patent, (copy attached as Exhibit "A"), entitled "Method For The Treatment Of Gastric Acid-Related Diseases And Production Of Medication Using (-)Enantiomer Of Omeprazole," was issued on March 2, 1999 to Astra Aktiebolag, upon assignment from the inventors Per Lindberg and Lars Weidolf. The patent was subsequently assigned to AstraZeneca AB. The '192 patent claims, *inter alia*, methods for treatment of gastric acid related diseases by administering a therapeutically effective amount of esomeprazole and pharmaceutically acceptable salts thereof and methods for producing a medicament for such treatment.

ANSWER: Sun admits that the '192 patent is entitled "Method For The Treatment Of Gastric Acid-Related Diseases And Production Of Medication Using (-) Enantiomer Of

Omeprazole," that a copy of the '192 patent is attached to the Complaint as Exhibit A, that the face of the patent states that it was issued on March 2, 1999, that the named inventors on the face of the patent are Per Lindberg and Lars Weidolf, and that Astra Aktiebolag is listed on the face of the '192 patent as assignee. Sun denies that the '192 patent was duly or legally issued. Sun is without knowledge or information to form a belief as to the truth of the allegation that the '192 has been assigned to AstraZeneca AB and therefore denies the same. The remainder of this Paragraph contains legal conclusions to which no response is required. To the extent a response is required, Sun denies the remaining allegations of this Paragraph.

19. Plaintiff AstraZeneca AB has been and still is the owner of the '192 patent. The '192 patent will expire on May 27, 2014 and pediatric exclusivity relating to the '192 patent expires on November 27, 2014.

ANSWER: Sun admits that the FDA Orange Book in connection with Esompeprazole Sodium for injection lists the expiration date of the '192 patent as May 27, 2014 and lists pediatric exclusivity associated with that patent as expiring on November 27, 2014. Sun lacks knowledge or information sufficient to form a belief about the remaining allegations of this Paragraph, and therefore denies the same.

20. In Sun's January 15, 2010 Letter, Sun notified Plaintiffs that, as part of its ANDA, it had filed a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") with respect to the '192 patent. This statutory section requires, *inter alia*, certification by the ANDA applicant that the subject patent, here the '192 patent, "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted ...." The statute (21 U.S.C. § 355(j)(2)(B)(iv)) also requires a Paragraph IV notice to "include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)) specify, *inter alia*, that a Paragraph IV notification must include "[a] detailed statement of the factual and legal basis of applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation."

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent a response is required, Sun admits that Sun FZE's January 15, 2010 Notice Letter notified Plaintiffs that Sun FZE filed ANDA No. 200-882 and that this letter contained a "Paragraph IV" certification with respect to the '192 patent, among others. Sun denies the remaining allegations of this Paragraph, including any suggestion that Sun FZE's January 15, 2010 Notice Letter failed to meet the requirements of any statutes or regulations, including any requirements set forth in 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c).

21. On information and belief, at the time Sun's January 15, 2010 Letter was served, Sun was aware of the statutory provisions and regulations referred to in paragraph 20 above.

ANSWER: Sun admits that it was aware of the statutes and regulations cited in Paragraph 20 at the time Sun FZE's January 15, 2010 Notice Letter was served. Sun denies the remaining allegations of this Paragraph.

22. Sun's January 15, 2010 Letter, which is required by statute and regulation to provide a full and detailed explanation regarding non-infringement (see paragraph 20 above), does not allege non-infringement of claims 1-6, 8-18 and 20-23 of the '192 patent.

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent a response is required, Sun states that Sun FZE's notice letter meets all statutory and regulatory requirements. Otherwise denied.

23. Even where asserted, Sun's January 15, 2010 Letter did not provide the full and detailed statement of its factual and legal basis to support its non-infringement and/or invalidity allegations as to the '192 patent.

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent a response is required, Sun states that Sun FZE's notice letter meets all statutory and regulatory requirements. Otherwise denied.

24. Sun conceded in its January 15, 2010 Letter that it did not comply with the laws and regulations cited in paragraph 20 above by stating "We do not need or undertake here to exhaust all reasonable invalidity or non-infringement arguments for each of these claims, and we do not take the position that all such arguments are exhausted in this opinion."

ANSWER: Sun admits that Sun FZE's January 15, 2010 Notice Letter contains the language quoted in this Paragraph. Sun denies the remaining allegations of this Paragraph.

25. In a letter dated January 29, 2010, Sun's outside litigation counsel further incorrectly stated that "there is no requirement that Sun's detailed statement exhaust all invalidity or non-infringement arguments for each of the claims."

ANSWER: Sun admits that a January 29, 2010 letter from Sun's counsel contains the language quoted in this Paragraph. Sun denies the remaining allegations of this Paragraph.

26. Accordingly, Sun's January 15, 2010 Letter fails to comply with the law, as specified in 21 U.S.C. § 355(j), and FDA rules and regulations, as specified in 21 C.F.R. § 314.95.

ANSWER: Denied.

27. By not addressing non-infringement of claims 1-6, 8-18 and 20-23 of the '192 patent in its January 15, 2010 Letter, Sun admits that its Esomeprazole Sodium I.V. Products meet all limitations of claims 1-6, 8-18 and 20-23 of the '192 patent.

ANSWER: Denied.

28. Sun infringed the '192 patent under 35 U.S.C. § 271(e)(2) by filing its ANDA seeking approval from the FDA to engage in the commercial manufacture, use or sale of a drug claimed in this patent, or the use of which is claimed in this patent, prior to the expiration of the '192 patent.

ANSWER: Sun admits that Sun FZE's filing of ANDA No. 200-882 containing a paragraph IV certification vests this Court with subject matter jurisdiction pursuant to 35 U.S.C. § 271(e) as to the patents listed therein and as to the party who submitted the ANDA. Sun denies the remaining allegations of this Paragraph.

29. On information and belief, Sun's Esomeprazole Sodium I.V. Products, if approved, will be administered to human patients in a therapeutically effective amount to treat gastric acid related diseases by inhibiting gastric acid secretion.

ANSWER: This Paragraph contains legal conclusions to which no response is required. This Paragraph further contains speculative allegations about actions that will allegedly occur if ANDA No. 200-882 is approved, to which no response is required. To the

extent a response is required, Sun refers to ANDA No. 200-882 for information concerning the product described therein. Otherwise denied.

30. On information and belief, such administration will decrease interindividual variation in plasma levels (AUC) during such treatment.

ANSWER: This Paragraph contains legal conclusions to which no response is required. This Paragraph further contains speculative allegations about actions that will allegedly occur if ANDA No. 200-882 is approved, to which no response is required. To the extent a response is required, Sun refers to ANDA No. 200-882 for information concerning the product described therein. Otherwise denied.

31. On information and belief, such treatment will increase average plasma levels (AUC) per dosage unit.

ANSWER: This Paragraph contains legal conclusions to which no response is required. This Paragraph further contains speculative allegations about actions that will allegedly occur if ANDA No. 200-882 is approved, to which no response is required. To the extent a response is required, Sun refers to ANDA No. 200-882 for information concerning the product described therein. Otherwise denied.

32. On information and belief, such treatment will effect a pronounced increase in gastrin levels in slow metabolizers during such treatment.

ANSWER: This Paragraph contains legal conclusions to which no response is required. This Paragraph further contains speculative allegations about actions that will allegedly occur if ANDA No. 200-882 is approved, to which no response is required. To the extent a response is required, Sun refers to ANDA No. 200-882 for information concerning the product described therein. Otherwise denied.

33. On information and belief, such treatment will effect decreased CYP1A induction in slow metabolizers during such treatment.

ANSWER: This Paragraph contains legal conclusions to which no response is required. This Paragraph further contains speculative allegations about actions that will allegedly occur if ANDA No. 200-882 is approved, to which no response is required. To the extent a response is required, Sun refers to ANDA No. 200-882 for information concerning the product described therein. Otherwise denied.

34. On information and belief, such treatment will elicit an improved antisecretory effect during such treatment.

ANSWER: This Paragraph contains legal conclusions to which no response is required. This Paragraph further contains speculative allegations about actions that will allegedly occur if ANDA No. 200-882 is approved, to which no response is required. To the extent a response is required, Sun refers to ANDA No. 200-882 for information concerning the product described therein. Otherwise denied.

35. On information and belief, such treatment will elicit an improved clinical effect comprising accelerated rate of healing and accelerated rate of symptom relief during such treatment.

ANSWER: This Paragraph contains legal conclusions to which no response is required. This Paragraph further contains speculative allegations about actions that will allegedly occur if ANDA No. 200-882 is approved, to which no response is required. To the extent a response is required, Sun refers to ANDA No. 200-882 for information concerning the product described therein. Otherwise denied.

36. On information and belief the amount to be administered will be between about 20 mg and about 40 mg total daily dose during such treatment.

ANSWER: This Paragraph contains legal conclusions to which no response is required. This Paragraph further contains speculative allegations about actions that will allegedly occur if ANDA No. 200-882 is approved, to which no response is required. To the

extent a response is required, Sun refers to ANDA No. 200-882 for information concerning the product described therein. Otherwise denied.

37. On information and belief, this administration will occur at Sun's active behest and with its intent, knowledge and encouragement.

ANSWER: This Paragraph contains legal conclusions to which no response is required. This Paragraph further contains speculative allegations about actions that will allegedly occur if ANDA No. 200-882 is approved, to which no response is required. To the extent a response is required, Sun refers to ANDA No. 200-882 for information concerning the product described therein. Otherwise denied.

38. On information and belief, Sun will actively encourage, aid and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '192 patent.

ANSWER: Denied.

39. On information and belief, Sun's Esomeprazole Sodium I.V. Products are especially made or especially adapted to inhibit gastric acid secretion and for use in the treatment of gastrointestinal inflammatory disease via the administration of a therapeutically effective amount of a pharmaceutical formulation containing the magnesium salt of esomeprazole. On information and belief, Sun is aware that its Esomeprazole Sodium I.V. Products are so made or so adapted.

ANSWER: This Paragraph contains legal conclusions to which no response is required. This Paragraph further contains speculative allegations about actions that will allegedly occur if ANDA No. 200-882 is approved, to which no response is required. To the extent a response is required, Sun refers to ANDA No. 200-882 for information concerning the product described therein. Otherwise denied.

40. On information and belief, Sun is aware that its Esomeprazole Sodium I.V. Products, if approved, will be used in contravention of Plaintiffs' rights under the '192 patent.

ANSWER: Denied.

41. On information and belief, the manufacture, use and sale of Sun's Esomeprazole Sodium I.V. Products infringe the '192 patent claims.

ANSWER: Denied.

42. To further investigate Sun's allegations of invalidity of the '192 patent, in a letter dated January 27, 2010, AstraZeneca requested access to certain documents and information.

ANSWER: Sun admits that in a letter dated January 27, 2010, AstraZeneca made unreasonable requests for documents and information in response to the Offer of Confidential Access contained in Sun FZE's January 15, 2010 Notice Letter. Sun is without knowledge or information sufficient for form a belief as to the truth of the remaining allegations in this Paragraph and therefore denies the same.

43. Sun failed to timely provide all requested confidential documents and information, thereby preventing AstraZeneca from fully investigating Sun's allegations. These actions show that Sun failed to provide an offer of confidential access to the application pursuant to statute (21 U.S.C. § 355(j)(5)(C)(i)(III)).

ANSWER: Denied.

44. Plaintiffs bring this suit, in part, to employ the judicial process and the aid of discovery to obtain under appropriate judicial safeguards information to confirm that Sun's Esomeprazole Sodium I.V. Products infringe valid claims of the '192 patent.

ANSWER: Sun is without knowledge or information sufficient for form a belief as to the truth of the allegations in this Paragraph and therefore denies the same.

AS TO THE SECOND CLAIM FOR RELIEF: '771 PATENT

45. Plaintiffs reallege paragraphs 1-16 above as if set forth specifically here.

ANSWER: Sun incorporates and repeats its responses to paragraphs 1-16 above.

46. The '771 patent, (copy attached as Exhibit "B"), entitled "Compounds," was issued on November 7, 2000 to AstraZeneca AB, upon assignment from the inventors Per Lennart Lindberg and Sverker Von Unge. The '771 patent claims, *inter alia*, esomeprazole sodium salts.

ANSWER: Sun admits that the '771 patent is entitled "Compounds," that a copy of the '771 patent is attached to the Complaint as Exhibit B, that the face of the patent states that it was issued on November 7, 2000, that the face of the patent lists AstraZeneca AB as assignee,

and that the named inventors on the face of the patent are Per Lennart Lindberg and Sverker von Unge. Sun denies that the '771 patent was duly or legally issued. The remainder of this Paragraph contains legal conclusions to which no response is required. To the extent a response is required, Sun denies the remaining allegations of this Paragraph.

47. Plaintiff AstraZeneca AB has been and still is the owner of the '771 patent. The '771 patent will expire on May 27, 2014.

ANSWER: Sun admits that the FDA Orange Book in connection with Esompeprazole Sodium for injection lists the expiration date of the '771 patent as May 27, 2014. Sun lacks knowledge or information sufficient to form a belief about the remaining allegations of this Paragraph and therefore denies the same.

48. In Sun's January 15, 2010 Letter, Sun notified Plaintiffs that as part of its ANDA it had filed a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") with respect to the '771 patent. This statutory section requires, *inter alia*, certification by the ANDA applicant that the subject patent, here the '771 patent, "is invalid or will not be infringed by the manufacture, use, offer to sale or sale of the new drug for which the application is submitted . . . ." The statute (21 U.S.C. § 355(j)(2)(B)(iv)) also requires a Paragraph IV notice to "include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)) specify, *inter alia*, that a Paragraph IV notification must include "[a] detailed statement of the factual and legal basis of applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds of supporting the allegation."

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent a response is required, Sun admits that Sun FZE's January 15, 2010 Notice Letter notified Plaintiffs that Sun FZE filed ANDA No. 200-882 and that this letter contained a "Paragraph IV" certification with respect to the '771 patent, among others. Sun denies the remaining allegations of this Paragraph, including any suggestion that Sun FZE's January 15, 2010 Notice Letter failed to meet the requirements of any statutes or regulations, including any requirements set forth in 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c).

49. On information and belief, at the time Sun's January 15, 2010 Letter was served, Sun was aware of the statutory provisions and regulations referred to in paragraph 48 above.

ANSWER: Sun admits that it was aware of the statutes and regulations cited in Paragraph 48 at the time Sun FZE's January 15, 2010 Notice Letter was served. Sun denies the remaining allegations of this Paragraph.

50. Sun's January 15, 2010 Letter, which is required by statute and regulation to provide a full and detailed explanation regarding non-infringement (see paragraph 48 above), does not allege non-infringement of any '771 patent claims.

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent a response is required, Sun states that Sun FZE's notice letter meets all statutory and regulatory requirements. Otherwise denied.

51. Even where asserted, Sun's January 15, 2010 Letter did not provide the full and detailed statement of its factual and legal basis to support its non-infringement and/or invalidity allegations as to the '771 patent.

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent a response is required, Sun states that Sun FZE's notice letter meets all statutory and regulatory requirements. Otherwise denied.

52. Sun conceded in its January 15, 2010 Letter that it did not comply with the laws and regulations cited in paragraph 48 above by stating "We do not need or undertake here to exhaust all reasonable invalidity or non-infringement arguments for each of these claims, and we do not take the position that all such arguments are exhausted in this opinion."

ANSWER: Sun admits that Sun FZE's January 15, 2010 Notice Letter contains the language quoted in this Paragraph. Sun denies the remaining allegations of this Paragraph.

53. In a letter dated January 29, 2010, Sun's outside litigation counsel further incorrectly stated that "there is no requirement that Sun's detailed statement exhaust all invalidity or non-infringement arguments for each of the claims."

ANSWER: Sun admits that a January 29, 2010 letter from Sun's counsel contains the language quoted in this Paragraph. Sun denies the remaining allegations of this Paragraph.

54. Accordingly, Sun's January 15, 2010 Letter fails to comply with the law, as specified in 21 U.S.C. § 355(j), and FDA rules and regulations, as specified in 21 C.F.R. § 314.95.

ANSWER: Denied.

55. By not addressing non-infringement of the '771 patent claims in its January 15, 2010 Letter, Sun admits that its Esomeprazole Sodium I.V. Products meet all limitations of the '771 patent claims.

ANSWER: Denied.

56. Sun infringed the '771 patent under 35 U.S.C. § 271(e)(2) by filing its ANDA seeking approval from the FDA to engage in the commercial manufacture, use or sale of a drug claimed in this patent, or the use of which is claimed in this patent, prior to the expiration of the '771 patent.

ANSWER: Sun admits that Sun FZE's filing of ANDA No. 200-882 containing a paragraph IV certification vests this Court with subject matter jurisdiction pursuant to 35 U.S.C. § 271(e) as to the patents listed therein and as to the party who submitted the ANDA. Sun denies the remaining allegations of this Paragraph.

57. On information and belief, Sun's Esomeprazole Sodium I.V. Products, if approved, will be administered to human patients in a therapeutically effective amount to treat gastric acid related diseases by inhibiting gastric acid secretion.

ANSWER: This Paragraph contains legal conclusions to which no response is required. This Paragraph further contains speculative allegations about actions that will allegedly occur if ANDA No. 200-882 is approved, to which no response is required. To the extent a response is required, Sun refers to ANDA No. 200-882 for information concerning the product described therein. Otherwise denied.

58. On information and belief, Sun's Esomeprazole Sodium I.V. Products, if approved, will be administered to human patients at Sun's active behest and with its intent, knowledge and encouragement. On information and belief, Sun will actively encourage, aid and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '771 patent.

ANSWER: This Paragraph contains legal conclusions to which no response is required. This Paragraph further contains speculative allegations about actions that will allegedly occur if ANDA No. 200-882 is approved, to which no response is required. To the extent a response is required, Sun refers to ANDA No. 200-882 for information concerning the product described therein. Otherwise denied, and specifically denied that the product described in ANDA No. 200-882, if used, would infringe any valid claim of the '771 patent.

59. On information and belief, Sun's Esomeprazole Sodium I.V. Products are especially made or especially adapted for treatment of humans. On information and belief, Sun is aware that its Esomeprazole Sodium I.V. Products are so made or so adapted. On information and belief, Sun is aware that its Esomeprazole Sodium I.V. Products, if approved, will be used in contravention of Plaintiffs' rights under the '771 patent.

ANSWER: This Paragraph contains legal conclusions to which no response is required. This Paragraph further contains speculative allegations about actions that will allegedly occur if ANDA No. 200-882 is approved, to which no response is required. To the extent a response is required, Sun refers to ANDA No. 200-882 for information concerning the product described therein. Otherwise denied, and specifically denied that the product described in ANDA No. 200-882, if used, would infringe any valid claim of the '771 patent.

60. On information and belief, Sun is aware that its Esomeprazole Sodium I.V. Products, if approved, will be used in contravention of Plaintiffs' rights under the '771 patent.

ANSWER: Denied.

61. On information and belief, the manufacture, use and sale of Sun's Esomeprazole Sodium I.V. Products infringe the '771 patent claims.

ANSWER: Denied.

62. To further investigate Sun's allegations of invalidity of the '771 patent, in a letter dated January 27, 2010, AstraZeneca requested access to certain documents and information.

ANSWER: Sun admits that in a letter dated January 27, 2010, AstraZeneca made unreasonable requests for documents and information in response to the Offer of Confidential

Access contained in Sun FZE's January 15, 2010 Notice Letter. Sun is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this Paragraph and therefore denies the same.

63. Sun failed to timely provide all requested confidential documents and information, thereby preventing AstraZeneca from fully investigating Sun's allegations. These actions show that Sun failed to provide an offer of confidential access to the application pursuant to statute (21 U.S.C. § 355(j)(5)(C)(i)(III)).

ANSWER: Denied.

64. Plaintiffs bring this suit, in part, to employ the judicial process and the aid of discovery to obtain under appropriate judicial safeguards information to confirm that Sun's Esomeprazole Sodium I.V. Products infringe valid claims of the '771 patent.

ANSWER: Sun is without knowledge or information sufficient for form a belief as to the truth of the allegations in this Paragraph and therefore denies the same.

AS TO THE THIRD CLAIM FOR RELIEF:
WILLFUL INFRINGEMENT AND EXCEPTIONAL CASE

65. Plaintiffs reallege paragraphs 1-64 above as if set forth specifically here.

ANSWER: Sun incorporates and repeats its responses to paragraphs 1-64 above.

66. In Sun's January 15, 2010 Letter, Sun notified Plaintiffs that as part of its ANDA it had filed a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") with respect to the '771 patent. This statutory section requires, *inter alia*, certification by the ANDA applicant that the subject patent, here the '771 patent, "is invalid or will not be infringed by the manufacture, use, offer to sale or sale of the new drug for which the application is submitted . . . ." The statute (21 U.S.C. § 355(j)(2)(B)(iv)) also requires a Paragraph IV notice to "include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)) specify, *inter alia*, that a Paragraph IV notification must include "[a] detailed statement of the factual and legal basis of applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds of supporting the allegation."

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent a response is required, Sun admits that Sun FZE's January 15, 2010

Notice Letter notified Plaintiffs that Sun FZE filed ANDA No. 200-882 and that this letter contained a "Paragraph IV" certification with respect to the '771 patent, among others. Sun denies the remaining allegations of this Paragraph, including any suggestion that Sun FZE's January 15, 2010 Notice Letter failed to meet the requirements of any statutes or regulations, including any requirements set forth in 21 U.S.C. § 355(j)(2)(B)(iv) and/or 21 C.F.R. § 314.95(c).

67. On information and belief, at the time Sun's January 15, 2010 Letter was served, Sun was aware of the statutory provisions and regulations referred to in paragraph 66 above.

ANSWER: Sun admits that it was aware of the statutes and regulations cited in Paragraph 66 at the time Sun FZE's January 15, 2010 Notice Letter was served. Sun denies the remaining allegations of this Paragraph.

68. Sun's January 15, 2010 Letter, which is required by statute and regulation to provide a full and detailed explanation regarding non-infringement (see paragraph 66 above), does not allege non-infringement of any '771 patent claims or '192 patent claims 1-6, 8-18 and 20-23.

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent a response is required, Sun states that Sun FZE's notice letter meets all statutory and regulatory requirements. Otherwise denied.

69. Even where asserted, Sun did not include a full and detailed statement of its factual and legal basis to support its non-infringement and/or invalidity allegations as to the '771 and '192 patents even though 21 C.F.R. § 314.95(c) requires that the January 15, 2010 Letter include "(i) *[f]or each claim* of a patent alleged not to be infringed, a *full and detailed explanation* of why the claim is not infringed" and "(ii) *[f]or each claim* of a patent alleged to be invalid or unenforceable, a *full and detailed explanation* of the grounds of supporting the allegation" (emphasis added).

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent a response is required, Sun states that Sun FZE's notice letter meets all statutory and regulatory requirements. Otherwise denied.

70. In addition, the invalidity bases alleged in Sun's January 15, 2010 Letter are speculative and without adequate foundation.

ANSWER: Denied.

71. Sun conceded in its January 15, 2010 Letter that it did not provide a full and detailed explanation, as required by the laws and regulations cited in paragraph 48 above, by stating "[w]e do not need or undertake here to exhaust all reasonable invalidity or non-infringement arguments for each of these claims, and we do not take the position that all such arguments are exhausted in this opinion."

ANSWER: Sun admits that Sun FZE's January 15, 2010 Notice Letter contains the language quoted in this Paragraph. Sun denies the remaining allegations in this Paragraph.

72. In a letter dated January 29, 2010, Sun's outside litigation counsel further incorrectly stated that "there is no requirement that Sun's detailed statement exhaust all invalidity or non-infringement arguments for each of the claims."

ANSWER: Sun admits that a letter dated January 29, 2010 from Sun's outside counsel contains the language quoted in this Paragraph. Sun denies the remaining allegations in this Paragraph.

73. Accordingly, Sun's January 15, 2010 Letter fails to comply with the law, as specified in 21 U.S.C. § 355(j), and FDA rules and regulations, as specified in 21 C.F.R. § 314.95.

ANSWER: Denied.

74. Sun's failure to provide a full and detailed explanation of non-infringement and invalidity positions for each claim of the '771 and '192 patents is willful.

ANSWER: Denied.

75. Sun's conduct in certifying to non-infringement and invalidity in its ANDA, providing a deficient, baseless and incomplete January 15, 2010 Letter and thereafter failing to remedy this deficiency when notified by AstraZeneca constitutes willful infringement.

ANSWER: Denied.

76. Sun's conduct in certifying to non-infringement and invalidity in its ANDA, providing a deficient, baseless and incomplete January 15, 2010 Letter and thereafter failing to remedy this deficiency when notified by AstraZeneca qualifies this case as exceptional.

ANSWER: Denied.

The "WHEREFORE" Paragraph following Paragraph 76 of the Complaint and the twelve lettered paragraphs that follow state Plaintiffs' prayer for relief, to which no response is required. To the extent a response is required, Sun denies the allegations set forth in the "WHEREFORE" Paragraph following Paragraph 76 and the twelve lettered paragraphs that follow and denies that Plaintiffs are entitled to any of the relief requested therein, or any relief whatsoever.

AFFIRMATIVE DEFENSES

First Affirmative Defense

The manufacture, use, offer for sale, sale or importation into the Unites States of the product described in ANDA No. 200-882 has not infringed, does not infringe, and would not infringe, if marketed, any valid and enforceable claims of the '192 and '771 patents, either directly or indirectly, and either literally or under the doctrine of equivalents.

Second Affirmative Defense

Claims of the '192 and '771 patents are invalid under one or more provisions of the U.S. Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103 and/or 112.

Third Affirmative Defense

Plaintiffs' Complaint fails to state a claim upon which relief may be granted.

Fourth Affirmative Defense

Any additional defenses or counterclaims that discovery may reveal.

The inclusion of a defense among the above-listed defenses is not an admission that Sun bears the burden of proof or persuasion on any claim or issue.

COUNTERCLAIMS

Defendants Sun Pharmaceutical Industries, Ltd., Sun Pharma Global FZE, and Sun Pharmaceutical Industries, Inc. ("Sun"), by way of counterclaim against Plaintiffs AstraZeneca AB, Aktiebolaget Hassle, AstraZeneca LP, KBI Inc., and KBI-E Inc. (collectively, "Counterclaim Defendants"), allege as follows:

THE PARTIES AND ACTS LEADING TO THESE COUNTERCLAIMS

1. Counterclaim Plaintiff Sun Pharmaceutical Industries, Ltd. is a company organized and existing under the laws of India having a principal place of business at Acme Plaza, Andheri -- Kurla Rd., Andheri (E), Mumbai, India 400059.

2. Counterclaim Plaintiff Sun Pharma Global FZE is a company organized and existing under the laws of the United Arab Emirates having a principal place of business at Office #43, SAIF Zone, P.O. Box 122304, Shariah, United Arab Emirates.

3. Counterclaim Plaintiff Sun Pharmaceutical Industries, Inc. is a company organized and existing under the laws of Michigan having a principal place of business at 279 Prospect Plains Rd., Cranbury, New Jersey 08512.

4. On information and belief, Counterclaim Defendant AstraZeneca AB is a company organized and existing under the laws of Sweden, having its principal place of business at Södertälje, Sweden.

5. On information and belief, Counterclaim Defendant Aktiebolaget Hassle is a company organized and existing under the laws of Sweden, having its principal place of business at Mölndal, Sweden.

6. On information and belief, Counterclaim Defendant AstraZeneca LP is a limited partnership organized under the laws of Delaware having its principal place of business at Wilmington, Delaware.

7. On information and belief, Counterclaim Defendant KBI, Inc. is a Delaware corporation having its principal place of business at Whitehouse Station, New Jersey.

8. On information and belief, Counterclaim Defendant KBI-E, Inc. is a Delaware corporation, having its principal place of business at Wilmington, Delaware.

9. Counterclaim Defendants allege that United States Patent No. 5,877,192 (the "'192 patent") was issued to Astra Aktiebolag and is currently owned by AstraZeneca AB.

10. Counterclaim Defendants allege that United States Patent No. 6,143,771 (the "'771 patent") is currently owned by AstraZeneca AB.

11. Counterclaim Defendants allege that KBI and KBI-E have exclusive rights in the '192 and '771 patents.

12. Sun FZE holds Abbreviated New Drug Application ("ANDA") No. 200-882 for Esomeprazole Sodium for Injection, 20 mg/vial and 40 mg/vial.

13. Counterclaim Defendants have alleged in the present action that Sun has infringed and will infringe the '192 and '771 patents by filing ANDA No. 200-882 with the FDA and/or manufacturing, using, offering for sale, selling or importing into the United States the products described in that ANDA.

14. As a consequence of the foregoing, there is an actual and justiciable controversy between Sun and Counterclaim Defendants as to whether the claims of the '192 and '771 patents are invalid, or whether those claims are being infringed or will be infringed by Sun's ANDA No. 200-882 or the products described therein.

JURISDICTION AND VENUE

15. This Court has jurisdiction over the subject matter of these counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338(a), in that the counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq*.

16. This court may declare the rights and other legal relations of the parties involved pursuant to 28 U.S.C. §§ 2201 and 2202 because this action is based on a case of actual controversy within the Court's jurisdiction seeking a declaratory judgment that the manufacture, use, offer for sale, sale and/or importation into the United States of the products described in Sun's ANDA No. 200-882 would not infringe the claims of the '192 and '771 patents, and that the claims of the '192 and '771 patents are invalid.

17. Venue for these counterclaims is proper within this judicial district pursuant to 28 U.S.C. § 1391(b).

COUNT I
Declaration of Invalidity of the '192 Patent

18. Sun realleges and incorporates by reference the allegations of paragraphs 1-17 of these Counterclaims and its above Answers to Paragraphs 1-76 of Plaintiffs' Complaint.

19. A present genuine and justiciable controversy exists between Sun and Counterclaim Defendants regarding, *inter alia*, the validity of the '192 patent.

20. Claims of the '192 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112.

21. Sun is entitled to a declaration that the claims of the '192 patent are invalid.

COUNT II
Declaration of Non-Infringement of the '192 Patent

22. Sun realleges and incorporates by reference the allegations of paragraphs 1-21 of the Counterclaims and its above Answers to Paragraphs 1-76 of Plaintiffs' Complaint.

23. A present genuine and justiciable controversy exists between Sun and Counterclaim Defendants regarding, *inter alia*, the issue of whether the manufacture, use, offer for sale, sale or importation of the products described in ANDA No. 200-882 would infringe claims of the '192 patent.

24. The manufacture, use, offer for sale, sale or importation of the products described in ANDA No. 200-882 would not infringe any valid claim of the '192 patent.

25. Sun is entitled to a declaration that the manufacture, use, offer for sale, sale or importation of products described in ANDA No. 200-882 would not infringe claims of the '192 patent.

COUNT III
Declaration of Invalidity of the '771 Patent

26. Sun realleges and incorporates by reference the allegations of paragraphs 1-25 of these Counterclaims and its above Answers to Paragraphs 1-76 of Plaintiffs' Complaint.

27. A present genuine and justiciable controversy exists between Sun and Counterclaim Defendants regarding, *inter alia*, the validity of the '771 patent.

28. Claims of the '771 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112.

29. Sun is entitled to a declaration that the claims of the '771 patent are invalid.

COUNT IV
Declaration of Non-Infringement of the '771 Patent

30. Sun realleges and incorporates by reference the allegations of paragraphs 1-29 of the Counterclaims and its above Answers to Paragraphs 1-76 of Plaintiffs' Complaint.

31. A present genuine and justiciable controversy exists between Sun and Counterclaim Defendants regarding, *inter alia*, the issue of whether the manufacture, use, offer for sale, sale or importation of the products described in ANDA No. 200-882 would infringe claims of the '771 patent.

32. The manufacture, use, offer for sale, sale or importation of the products described in ANDA No. 200-882 would not infringe any valid claim of the '771 patent.

33. Sun is entitled to a declaration that the manufacture, use, offer for sale, sale or importation of products described in ANDA No. 200-882 would not infringe claims of the '771 patent.

PRAYER FOR RELIEF

WHEREFORE, Sun respectfully requests that this Court enter a Judgment and Order in its favor and against Plaintiffs/Counterclaim Defendants as follows:

A. Dismissing the Complaint with prejudice;

B. Declaring that the claims of U.S. Patent No. 5,877,192 are invalid;

C. Declaring that any valid claims of U.S. Patent No. 5,877,192 are not and will not be infringed by the manufacture, use, offer for sale, sale or importation of the products described in Sun FZE's ANDA No. 200-882;

D. Declaring that the claims of U.S. Patent No. 6,143,771 are invalid;

E. Declaring that any valid claims of U.S. Patent No. 6,143,771 are not and will not be infringed by the manufacture, use, offer for sale, sale or importation of the products described in Sun FZE's ANDA No. 200-882;

F. Declaring that this case is exceptional under 35 U.S.C. § 285 and awarding Sun its attorneys' fees, costs, and expenses in this action;

G. Enjoining Plaintiffs/Counterclaim Defendants and persons or entities under their control from threatening or charging infringement of, or instituting or maintaining any action for infringement of U.S. Patent Nos. 5,877,192 or 6,143,771 against Sun or any related entities on account of the manufacture, use, offer for sale, sale or importation of any products described in ANDA No. 200-882;

I. Awarding its costs; and

J. Awarding such other and further relief as may be appropriate.

WINSTON & STRAWN LLP
Attorneys for Defendants
Sun Pharma Global FZE, Sun Pharmaceutical Industries, Inc., and Sun Pharmaceutical Industries, Ltd.

By: s/ James S. Richter
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Dated: April 6, 2010

OF COUNSEL:
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JURY DEMAND

Sun demands trial by jury as to all issues so triable.

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Dated: April 6, 2010

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 AND 40.1

Pursuant to Local Civil Rules 11.2 and 40.1, the undersigned counsel for Sun certifies that, to the best of his knowledge, information and belief, United States Patent No. 5,877,192 asserted in this case is also being asserted in the following pending patent cases:

AstraZeneca AB et al. v. Lupin Ltd. et al., No. 3:09-cv-5405 (D.N.J.)

AstraZeneca AB et al. v. Sandoz, Inc., No. 3:09-cv-199 (D.N.J.)

AstraZeneca AB et al. v. Dr. Reddy's Laboratories, Ltd. et al., No. 3 :08-cv-328 (D.N.J.)

s/ James S. Richter
James S. Richter

Dated: April 6, 2010

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

Pursuant to Local Civil Rule 201.1, the undersigned counsel for Sun hereby certifies that as a result of the nature of Sun's causes of action, as asserted in its counterclaims, this action is not appropriate for compulsory arbitration.

s/ James S. Richter
James S. Richter

Dated: April 6, 2010

CERTIFICATION OF SERVICE

The undersigned attorney certifies that a copy of the foregoing ANSWER, AFFIRMATIVE DEFENSES, COUNTERCLAIMS AND JURY DEMAND was served by ECF and electronic mail on the 6th day of April, 2010 upon:

Jonathan M. Short

MCCARTER &ENGLISH
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102

s/James S. Richter
James S. Richter

Dated: April 6, 2010